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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,026	01/18/2002	Tadashi Mukai	06854.0011	8884

7590 10/28/2002

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EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

12

DATE MAILED: 10/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,026

Applicant(s)

MUKAI ET AL.

Examiner

Donna A. Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 15-19, 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 20-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 4, 5. 6) ☐ Other: .

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-14 and 20-26 in Paper No. 11 is acknowledged.

Claims 15-19 and 27-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Claims 1-14 and 20-26 are presented for examination

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Patel et al. U.S. Patent No. 6,294,192 B1.

The claims are drawn to a pharmaceutical composition comprising cilostazol in a fine powder and a solubilizing agent such as sodium lauryl sulfate.

Patel et al. teach cilostazol, a hydrophobic therapeutic agent (see abstract) combined with surfactants such as sodium lauryl sulfate (column 18, lines 14-34).

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Regarding the particle size, it is typically 20 nm or less in average diameter (column 28, line 41 to column 30, line 35).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otsuka Pharmaceutical Co. LTD, WO 97/48382 A2 in view of Patel et al., U.S. Patent No. 6,294,192 B1.

The claims are drawn to a pharmaceutical composition comprising cilostazol in a fine powder and a solubilizing agent such as sodium lauryl sulfate, the composition

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being in a sustained release preparation and wherein a sustained release outer layer is released more slowly than the core.

Otsuka Pharmaceutical Co. teaches cilostazol in the form of a prolonged release drug (see abstract). Multiple-unit type prolonged release drug preparations are set forth (see examples).

It does not teach the particle size claimed.

Regarding the particle size, Patel et al. teach cilostazol, a hydrophobic therapeutic agent (see abstract) combined with surfactants such as sodium lauryl sulfate (column 18, lines 14-34) and a particle size of 20 nm or less in average diameter (column 28, line 41 to column 30, line 35). Patel et al. provides motivation to place a hydrophobic compound in an ionic surfactant such as sodium lauryl sulfate in a fine particle size. Otsuka Pharmaceutical Co. provides motivation for one to solve the problem of the cilostazol causing side-effects such as headache, caused by the high concentration of cilostazol released into the blood, by formulating a sustained release preparation wherein 2 small tablets are place in a sustained release preparation wherein one releases earlier than the other. Thus, by combining the teachings of Patel et al. and Otsuka Pharmaceutical Co. one would have been motivated to prepare a formulation of sustained release cilostazol with a fine particle size and an alkyl sulfate surfactant.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

No claims are allowed.


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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna A. Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached from 8:00 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


dj
October 17, 2002

FREDERICK KRASS
PRIMARY EXAMINER
GROUP 1600
